February 21, 2018

Synedgen, Inc
Shenda Baker
President and Chief Operating Officer
1420 N. Claremont Blvd., Suite 105D
Claremont, California 91711

Re: K172338
Trade/Device Name: Catasyn Advanced Technology Wound Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 15, 2018
Received: January 19, 2018

Dear Shenda Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172338

Device Name
Catasyn Advanced Technology Wound Hydrogel

Indications for Use *(Describe)*
Catasyn OTC is indicated for the dressing and management of minor burns, minor cuts, minor lacerations, minor abrasions, and minor irritations of the skin.

Catasyn may be used under the direction of a health care professional for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites) and superficial and partial thickness (second degree) burns.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K172338

Synedgen, Inc.

Catasyn Advanced Technology Wound Hydrogel

Submitter:

Synedgen, Inc.
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Claremont, CA 91711
Phone: 909-447-6858
Fax: 909-447-6801
Contact Person: Shenda Baker
Date Prepared: February 15, 2018

Device:

Name of Device: Catasyn Advanced Technology Wound Hydrogel

Common or Usual name: Hydrogel Wound Dressing

Classification: Unclassified

Product Code: FRO

Primary Predicate Device:

Bionect Clear Hydrogel (K973725 RX) (K984264 OTC) (FRO)
This predicate has not been subject to a design-related recall.

Reference Predicate Devices:

SynePure (K143444) (KMF)
IPM Wound Gel Bio/ IPM Derm Gel Bio 1 (K143527) (FRO)
Atteris Antimicrobial Skin and Wound Cleanser (K160192) (FRO)
MimyX Cream (K041342) (MGQ)

Device Description:

Catasyn is a clear, colorless hydrogel that is composed of hypromellose, arginine derivatized chitosan, betaine, and methylparaben to form a hydrogel dressing. The device is a non-sterile, preserved hydrogel. The gel is supplied in 0.07oz. (2mL), 0.85oz (25mL), or 3oz (88.7mL) tubes.

Catasyn is a wound hydrogel that provides a moist wound environment. A moist wound environment is supportive to wound healing.

Indications for use:

Catasyn OTC is indicated for the dressing and management of minor burns, minor cuts, minor lacerations, minor abrasions, and minor irritations of the skin.

Catasyn RX may be used under the direction of a health care professional for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites) and superficial and partial thickness (second degree) burns.

Performance data:

Biocompatibility Testing

Test	Descriprion	Result
Cytotoxicity Direct Contact	Cytotoxicity was evaluated using ISO-10993-5, Biological evaluation of Medical Devices-Part 5: *Tests for In Vitro Cytotoxicity*.	Non-toxic
Maximization Test For Delayed-Type Hypersensitivity	Delayed-type hypersensitivity was evaluated according to ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for Irritation and skin sensitization.*	No Sensitization reaction was observed in any of the test animals
Dermal Irritation	Dermal irritation was evaluated according to ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*	No erythema or edema (was observed. The Primary Irritation Index for the test article was 0.
Acute Systemic Toxicity	Acute systemic toxicity was tested according to ISO 10993-11, *Biological Evaluation of Medical Devices – Tests for Systemic Toxicity.*	No Biological reactivity was observed at any time point
Hemolysis extraction method and direct contact	Hemolysis was tested according to ASTM 756-13 for both extraction and direct contact methods.	The corrected hemolytic index was 0% for extraction and direct contact. The test article is considered non-hemolytic.

Preservation

Catasyn was tested for it preservative effectiveness and meets the category 2 challenge by USP 51 immediately following production and at the 6-month shelf life test point. The product will continue to be challenged at 12,18, 24, 30, and 36 months testing.

Shelf life

The first study of stability incorporated three lots of the device including each tube type and is schedule for 36 months. The current data for real time aging of the samples indicate the product meets its specification after 9 months.

Comparison with predicate:

The candidate device, Catasyn, has the same intended use and substantially equivalent technological characteristics as the predicate device, Bionect Clear Hydrogel. Both the predicate and candidate device contain aqueous based viscous, highly hydrated, and lubricating gels. The gels are composed primarily of water with the addition of thickeners and moisturizers. Both gels are supplied non-sterile and contain preservatives to extend shelf life. Like the predicate device, Catasyn provides a moist environment for wound healing of skin wounds and burns.

Comparison of New and Predicate Devices

	New Device (Catasyn Advanced Technology Wound Hydrogel)	Predicate Device (Bionect Clear Hydrogel)
Intended Use	Dermal wounds	Dermal wounds
OTC	Catasyn OTC is indicated for the dressing and management of minor burns, minor cuts, minor lacerations, minor abrasions, and minor irritations of the skin.	Bionect OTC is indicated for the dressing and management of minor burns; superficial cuts, lacerations, and abrasions; and minor irritations of the skin.
Indications for Rx	Catasyn RX may be used under the direction of a health care professional for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites) and superficial and partial thickness (second degree) burns.	Bionect may also be used under the care of a health care professional for wounds such as partial to full thickness dermal ulcers (pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers), surgical wounds (post-operative incisions and donor sites), and 2nd degree burns.
Sterile or preservative	Non-sterile, preserved	Non-sterile, preserved
Composition	USP Purified water Hypromellose Chitosan derivatives (arginine derivatized chitosan) NF Methylparaben Betaine	Purified water Hyluronic acid Carbomer 980 Sorbitol Sodium dehdroacetate Methylparaben, Propylparaben Sodium hydroxide
Packaging	0.07oz. (2mL), 0.85oz (25mL), or 3oz (88.7mL) LDPE tubes	100 gram LDPE tube
Shelf Life	Current real time aging studies support 9 months	Up to 24 months
Mode of action	Provides a moist wound environment that is supportive to wound healing.	Provides a moist environment that is supportive to wound healing.

Conclusions:

Based on the Indications for Use and the data presented in this submission, Catasyn Advanced Technology Wound Hydrogel is substantially equivalent to the predicate device (K973725).